IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA CLARKSBURG

FRANCES G. POST, individually and on behalf of all others similarly situation,

Plaintiff,

v.

Civ. Action No. 1:19-CV-73 (Judge Kleeh)

AMERISOURCEBERGEN CORPORATION,
a Delaware corporation, US
BIOSERVICES CORPORATION, a
Delaware corporation, Ig.G. OF
AMERICA, INC., a Maryland corporation,
and IHS ACQUISITION XXX, INC., a Delaware
Corporation,

Defendants.

MEMORANDUM ORDER DENYING DEFENDANTS' MOTION TO DISMISS [DKT. NO. 15]

On March 30, 2020, this Court issued an Order [Dkt. No. 36] denying in part and granting in part Defendants' Motion to Dismiss [Dkt. No. 15] further noting that a memorandum opinion would follow. For the reasons discussed herein, that Order is AMENDED to the extent that the motion to dismiss [Dkt. No. 15] is DENIED as to Counts I, II, III, IV, V, and VI, and DENIED AS MOOT as to Count VII. The Court further DENIES the motion to dismiss based on The Medical Professional Liability Act ("MPLA").

PROCEDURAL HISTORY

On April 18, 2019, the Plaintiff filed a Complaint against

Defendants AmerisourceBergen Corporation ("AmerisourceBergen"), US Bioservices Corporation ("US Bioservices"), I.g.G. of America, Inc. ("I.g.G."), and IHS Acquisition XXX, Inc. ("IHS") (collectively, "Defendants") [Dkt. No. 1]. An Amended Complaint was filed on May 8, 2019 [Dkt. No. 9]. Defendants filed a Motion to Dismiss on July 15, 2019 [Dkt. No. 15], to which Plaintiff responded on August 7, 2019 [Dkt. No. 19]. Defendants filed a reply on August 20, 2019 [Dkt. No. 20] which makes the matter ripe for consideration.

I. FACTUAL BACKGROUND

Plaintiff, Frances G. Post ("Post" or "Plaintiff"), alleges seven claims in this matter: Count I, Negligence; Count II, Personal Injury; Count III, Civil Conspiracy; Count IV, Fraudulent Concealment; Count V, Unjust Enrichment/Disgorgement; Count VI, Breach of Confidentiality and Violation of Privacy; and Count VII, Punitive Damages [Dkt. No. 9]. Post is a resident of Morgantown, West Virginia and alleges that she, and putative class members, are individuals who were directed by Felix Brizuela, D.O. ("Brizuela") to purchase immunogloblin ("IVIG") from Defendants in Morgantown, West Virginia¹ [Id. at 2]. IVIG is an intravenously

For purposes of the Motion to Dismiss, the Court accepts as true the facts alleged in the Amended Complaint. See Anderson v. Sara Lee Corp., 508 F.3d 181, 188 (4th Cir. 2007) (quoting Erickson v. Pardus, 551 U.S. 89, 94 (2007)).

administered blood product prepared by pooling immunoglobulins from the plasma of thousands of human donors [Id. at 5]. Plaintiff alleges that I.g.G. employed an Executive Account Manager and Director of Sales to target Felix Brizuela, D.O., among other physicians, to achieve an increase in sales of IVIG and to increase the profits of AmerisourceBergen, US Bioservices, I.g.G, and IHS Acquisition² [Id. at 5-6]. Plaintiff asserts that Defendants made

² Felix Brizuela, D.O. is a Doctor of Osteopathic Medicine and a board-certified neurologist with a neurology practice Morgantown, West Virginia [Dkt. No. 19 at 2, n.1]. A federal grand jury indicted Brizuela on 21 counts of distributing controlled substances outside the bounds of professional medical practice, in violation of 21 U.S.C. §§ 841(a)(1), (b)(1)(C); one count of conspiracy to distribute controlled substances outside the bounds of professional medical practice, in violation of 21 U.S.C. §§ 841(a)(1), (b)(1)(E)(i), (b)(1)(E)(iii); and 16 counts of illegal remuneration in violation of the federal anti-kickback statute, in violation of 42 U.S.C. §§ 1320a-7b(b)(1)(B) [N.D. W.Va. Criminal Action No: 1:18-cr-00001, Dkt. No. 1]. The anti-kickback charges related to a financial arrangement involving Brizuela, Southwest Laboratories, LLC ("Southwest"), and Medspan Laboratory, Inc. In January 2019, Brizuela was tried and ("Medspan") [Id.]. convicted of certain felony offenses related to services he provided at a pain management and/or suboxone clinic and opioid prescribing practices in his private practice [Dkt. No. 19 at 2, n.1]. On June 19, 2020, the United States Court of Appeals for the Fourth Circuit reversed the conviction and remanded the case for a new trial. United States v. Felix Brizuela, Jr., No. 19-4656, --- F.3d ---, 2020 WL 3393440 (4th Cir. 2020). The reversal of Brizuela's conviction was based on his contention that, under United States v. Kennedy, 32 F.3d 876 (4th Cir. 1994) and Federal Rule of Evidence 404(b), the district court improperly admitted the testimony of patients whose treatment was not the basis for any of the charges in the indictment. Brizuela, 2020 WL 339440, at *2. The Fourth Circuit determined that the government did not establish that the error was harmless and vacated the conviction. Id. at *3. On remand, Brizuela pled guilty to Count 2 of the Indictment, distribution of controlled substances outside the bounds of professional medical practice in violation of 21 U.S.C.

payments to Felix Brizuela, D.O. to induce him to misdiagnose patients and wrongfully disclose sensitive, private, and protected medical information of Plaintiff and other putative class members for the purpose of increasing new-book sales of IVIG, which increased Defendants' profits [Id. at 5].

For the period relevant to the allegations in the Amended Complaint, Felix Brizuela, D.O. and Felix Brizuela, D.O., PLLC operated a neurology office located at 1271 Suncrest Towne Centre, Morgantown, West Virginia [Dkt. No. 9 at 5]. Plaintiff contends Defendants greatly incentivized the aggressive sale of IVIG, especially to new purchasers, because Defendants knew: (1) once a person is prescribed IVIG, the person will likely take IVIG infusions for the remainder of his/her natural life; (2) IVIG is expensive for the purchaser and lucrative for Defendants; and (3) Defendants devised an internal practice which enabled them to secretly under report and under pay bonus commissions on IVIG sales to bolster corporate profits [Id. at 6]. Plaintiff asserts that Defendants charged high rates for the IVIG product and increased prices as the customer continued to purchase IVIG [Id.].

Plaintiff claims to have received infusions every two weeks at an initial charge of \$8,758.29 for each infusion [Dkt. No. 9 at

^{§§ 841(}a)(1) and 841(b)(1)(C) [N.D. W.Va. Criminal Action No: 1:18-cr-1-1, Dkt. No. 494]. Brizuela was sentenced on October 1, 2020, and the government dismissed the remaining charges in the Indictment [Id., Dkt. No. 495].

6]. The cost to Plaintiff was then raised to \$9,126.28 and \$10,450.44, respectively, for each infusion over a period of approximately twelve (12) months [Id.]. Plaintiff contends that Defendants so aggressively incentivized bonus commissions to its sales executives to book IVIG transactions that some sales executives earned an IVIG quarterly bonus in excess of \$900,000.00, and that sales executives received a higher bonus commission percentage for the first six months of every new-book IVIG transaction [Id.].

Plaintiff alleges that on April 3, 2012, Defendants began making payments to Felix Brizuela, D.O., that were unlawful, wrongful, violated Defendants' written policies, violated ethical standards, and placed the health, safety, and wellbeing of Plaintiff and putative class members at risk [Dkt. No. 9 at 7]. The payments made by Defendants to Brizuela continued until March 19, 2015 [Id.]. Plaintiff claims that Brizuela performed no services for Defendants to earn the payments made to him other than increasing the number of new-book IVIG transactions [Id.]. While Defendants paid Felix Brizuela, D.O. to obtain new-book IVIG transactions, Brizuela became one of the highest volume IVIG prescribing practitioners in the United States as measured by data from the Centers for Medicare and Medicaid Services ("CMS") [Id.]. During the approximate 26-month period Defendants made payments to Felix Brizuela, D.O., Defendants obtained approximately 65 new-

book IVIG transaction accounts through Brizuela [Id.]. Defendants also obtained numerous additional new referrals from Brizuela during that same period for whom Defendants attempted to obtain pre-authorization payment approval [Id.].

Plaintiff alleges that neither she, nor the putative class members, had CIPD, the medical condition diagnosed to trigger the sale of IVIG [Dkt. No. 9 at 7]. Plaintiff asserts that Defendants knew Felix Brizuela, D.O. was making CIDP diagnoses to trigger the sale of IVIG at an incident rate exponentially higher than any rate published in peer review studies, higher than any other prescribers, and that Brizuela's documentation in the possession of Defendants did not support new-book IVIG transactions [Id.]. It is further alleged that Defendants knew the health, safety, and wellbeing of Plaintiff and punitive class members were at risk because Defendants were making improper payments to obtain new-book IVIG transactions through Brizuela [Id. at 8].

According to the Amended Complaint, IVIG is infused slowly over a course of hours, and it requires surgical PICC line placement and placement for infusion or IV administration for each infusion [Dkt. No. 9 at 8]. Both methods of infusion are associated with risk of infection, injury, disease, and death [Id.]. Side effect rates for IVIG are high and include extreme fatigue, malaise, fever, nausea vomiting, all described as flulike symptoms, headaches, blood pressure changes, and tachycardia

[Id.]. Plaintiff asserts the infusions prevent people from carrying out functions of daily living and work on the days of their infusion, and for some days, thereafter [Id.]. Plaintiff further claims that IVIG is associated with acute renal failure, thromboembolic events, aseptic meningitis, neutropenia, and skin reactions, among other risks [Id.]. All IVIG patients require administration and monitoring associated with the infusions [Id.].

The allegations state that Felix Brizuela, D.O. performed no services on behalf of Defendants to legitimately earn ten (10) payments made to Brizuela by and on behalf of Defendants [Dkt. No. 9 at 8]. Plaintiff contends that Defendants admit the payments to Brizuela violate their own policies, and that those policies were put in place, in part, to protect the health, safety, and wellbeing of IVIG purchasers, including Plaintiff and the other putative class members [Id.]. Plaintiff alleges that Defendants made the improper payments to Brizuela and violated their own policies to increase new-book IVIG transactions, increase paid and underpaid sales commissions, and increase corporate profits [Id. at 8-9]. Plaintiff further contends that the Defendants' wrongful actions were concealed from Plaintiff and putative class members, and that Plaintiff became aware of the wrongful payments in April 2019 [Id. at 9].

Plaintiff's Amended Complaint is brought individually and on behalf of the putative class members she seeks to represent [Dkt.

No. 9 at 9]. Plaintiff defines the proposed class as follows:

All persons who were prescribed immunoglobulin (IVIG) by Felix Brizuela, D.O. between April 3, 2012 and March 19, 2015 and were directed to Defendants AmerisourceBergen Corporation, US Bioservices Corporation, Ig.G. of America, Inc., and IHS Acquisition XXX, Inc. for purchase of IVIG.

[Id. at 9].

II. STANDARD OF REVIEW

Rule 12(b)(6) of the Federal Rules of Civil Procedure allows a defendant to move for dismissal upon the ground that a complaint does not "state a claim upon which relief can be granted." In ruling on a motion to dismiss, a court "must accept as true all of the factual allegations contained in the complaint." Anderson v. Sara Lee Corp., 508 F.3d 181, 188 (4th Cir. 2007) (quoting Erickson v. Pardus, 551 U.S. 89, 94 (2007)). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986). A court also liberally construes "the complaint, including all reasonable inferences therefrom, ... in Plaintiff's favor." Estate of Williams—Moore v. All. One Receivables Mgmt., Inc., 335 F. Supp. 2d 636, 646 (M.D.N.C. 2004) (citations omitted).

A motion to dismiss under Rule 12(6)(b) tests the "legal sufficiency of a complaint." Francis v. Giacomelli, 588 F.3d 186, 192 (4th Cir. 2009). A court should dismiss a complaint if it does not contain "enough facts to state a claim to relief that is

plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). Plausibility exists "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). To withstand a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must plead enough facts "to state a claim to relief that is plausible on its face." Wikimedia Found. v. Nat'l Sec. Agency, 857 F.3d 193, 208 (4th Cir. 2017) (quoting Ashcroft, 556 U.S. at 678 (2009)). The factual allegations "must be enough to raise a right to relief above a speculative level." Twombly, 550 U.S. at 545. The facts must constitute more than "a formulaic recitation of the elements of a cause of action." Id. at 555. A motion to dismiss "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." Republican Party of N.C. v. Martin, 980 F.2d 942, 952 (4th Cir. 1992).

III. DISCUSSION

Defendants ask the Court to dismiss all claims in the Amended Complaint. The Court will discuss each in turn.

A. Negligence and Personal Injury

Defendant requests dismissal of Plaintiff's Negligence and Personal Injury claims at Counts I and II of the Amended Complaint³

³ Defendants note that Count I of the Amended Complaint is titled "Negligence," while Count II is titled "Personal Injury."

[Dkt. No. 15]. Defendants argue that Plaintiff fails to state a claim because Plaintiff relies on statutory violations, under the Stark Act, 42 U.S.C. § 1395nn, and the Anti-Kickback law, 42 U.S.C. § 1320a-7b, for which no private right of action exists [Dkt. No. 15-2 at 3]. The Stark Act prohibits a physician who has a financial relationship with an entity from making a referral to that entity for the furnishing of certain services for which payment may be made by the federal government under the Medicare program. See 42 U.S.C. § 1395nn. The Anti-Kickback law is a criminal statute that prohibits the knowing and willful solicitation and/or receipt of remuneration in return for referring a patient for the furnishing of an item or service for which payment may be made in whole or in part under a federal health care program. See 42 U.S.C. § 1320a-Defendants argue that rights under the Anti-Kickback statute are only enforceable through the qui tam provisions of the False Claims Act [Dkt. No. 15-2 at 4].

In the alternative, Defendants argue that there exists no common law duty of care as between Plaintiff and Defendants, and that Plaintiff's negligence claims are barred by the economic loss rule [Dkt. No. 15-2 at 6-9]. Defendants also submit that

Defendants argue that personal injury is a form of injury or category of damages recoverable in a negligence action, and not an independent cause of action. Defendants address Count II as part of their argument to dismiss the negligence claim in Count I [Dkt. No. 15-2 at 2, n.2], and the Court will address both counts together.

Plaintiff's negligence claims must fail because one cannot negligently aid and abet the tortious acts of another [Id. at 9-11]. They further contend that even if Defendants were negligent, the alleged acts of Felix Brizuela, D.O., were an intervening and superseding cause that breaks the chain of liability [Id. at 12].

Plaintiff responded to Defendants' motion to dismiss by first noting that Plaintiff has not alleged causes of action under either the Stark Act or Anti-Kickback Law [Dkt. No. 19 at 11]. Plaintiff asserts that the statutes do not prohibit a person from asserting state tort claims based on conduct that results in personal injuries and damages where the conduct may also violate federal regulatory standards or criminal statutes [Id.]. contends that Defendants owed a duty of care to prevent the likely foreseeable injuries to Plaintiff and putative class members, and that Plaintiff has alleged detailed and specific examples of wrongful conduct by Defendants which created a foreseeable, and unreasonable risk of harm to Plaintiff and potential class members [Id. at 6-8]. Plaintiff argues that West Virginia law recognizes a cause of action of tortious concert of action and that Defendants can, in fact, be held liable for the tortious concert of action asserted against them [Id. at 9]. Finally, Plaintiff contends that Defendants' conduct was a substantial factor in causing Plaintiff's alleged injuries and that they are not relieved from liability by the acts of Felix

Brizuela, D.O. [Id. at 13].

The Court agrees that Plaintiff has not alleged violations of the Stark Act or the Anti-Kickback Law in the Amended Complaint. While civil suits are not uncommon under the Anti-Kickback Law, they primarily take the form of a qui tam action under the False Claims Act ("FCA")⁴. Defendants fail to provide the Court with precedential authority establishing that conduct which may violate the Stark Act and the Anti-Kickback Law can never be the basis for a lawsuit under a different statute or legal theory.

Here, Plaintiff does not allege violations of the FCA or causes of action under the Stark Act⁵ or Anti-Kickback Law as grounds for recovery. Rather, she brings a common law negligence claim and claim for personal injuries related to Defendants' conduct in providing wrongful, substantial assistance, and encouragement to Felix Brizuela, D.O. to diagnose CIDP and increase

⁴ One example of such a suit that came to the Court's attention in researching this issue involves one of the Defendants in this matter. US Bioservices entered into a stipulation and order of settlement and dismissal in the United States District Court for the Southern District of New York in an Anti-Kickback and FCA case arising from a remuneration arrangement with Novartis Pharmaceutical Corporation ("Novartis") [United States of America v. U.S. Bioservices Corp., No. 1:17-cv-6353-CM, Dkt. No. 5].

⁵ The Stark Act gives no one the right to sue and never appears in court alone. It always travels as a companion of another statute that creates a cause of action, typically, the False Claims Act. See <u>United States ex rel. Bookwalter v. UPMC</u>, 946 F.3d 162, 169 (3rd Cir. 2019). A Medicare claim that violates the Stark Act is a false claim under the FCA. Id. (citation omitted).

Defendants' new-book IVIG transactions at an increased profit to Defendants. Plaintiff alleged that Defendants paid Brizuela from April 3, 2012 to March 19, 2015, in exchange for increasing Defendants' number of new-book IVIG transactions. Given the allegations, dismissal of Counts I and II because the Stark Act and Anti-Kickback Law prohibit any and all private claims is not See Braun v. Promise Regional Medical Centerwarranted. Huntchinson, Civ. A. 11-2180, 2011 WL 6304119 (U.S.D.K. Dec. 16, 2011) (finding that the Stark Act does not limit the authority of a court to grant relief for unjust enrichment and it is not presumed that the common law is changed by the passage of a statute which gives no indication that it proposes such a change); State ex rel. Van Nguyen v. Berger, 483 S.E.2d 71 (W. Va. 1996) (explaining that common law is not to be construed as altered or changed by statute, unless legislative intent to do so be plainly manifested).

The Court also cannot find that Plaintiff failed to sufficiently plead a claim for negligence based on lack of duty by Defendants. "In order to establish a prima facie case of negligence in West Virginia, it must be shown that the defendant has been guilty of some act or omission in violation of a duty owed to the plaintiff. No action for negligence will lie without a duty broken." Syl. Pt. 1, Parsley v. General Motors Acceptance Corporation, 280 S.E.2d 703 (W. Va. 1981). A duty exists when a

person "engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another." Robertson v. LeMaster, 301 S.E.2d 563, 567 (W. Va. 1983) (citing Restatement (Second) of Torts § 321 (1965)). Under these circumstances, a duty exists to exercise reasonable care to prevent the threatened harm. Id. "The obligation to refrain from particular conduct is owed only to those who are foreseeably endangered by the conduct and only with respect to those risks or hazards whose likelihood made the conduct unreasonably dangerous." Id. at 568 (citation omitted).

Foreseeability is the "ultimate test" of whether a duty of care exists. Syl. Pt. 8., Aikens v. Debow, 541 S.E.2d 576 (W. Va. 2000). This asks whether an ordinary man in the defendant's position, considering what he knew or should have known, would have anticipated the general harm suffered would likely occur. Id. at 581. While foreseeability is necessary to establish a duty of care, the court can also consider "the core issue of the scope of the legal system's protection, including the likelihood of injury, the magnitude of burden of guarding against it, and the consequences of placing that burden on defendant." Bilmar Ltd. P'ship v. Prima Mktg., LLC, Civ. A. No. 2:13-1439, 2013 WL 6195722, at *4 (S.D. W. Va. Nov. 27, 2013) (citations omitted). When a case involves a physical injury, a special relationship analysis

is not required to find a duty of care. <u>Bragg v. United States</u>, 741 S.E.2d 90, 99 (W. Va. 2013).

The Amended Complaint contains sufficient facts to support a negligence claim. Plaintiff alleged affirmative conduct by Defendants in making payments to Felix Brizuela, D.O. to increase IVIG transactions, and in concealing from patients information regarding the payments and the increased number of CIPD diagnoses in the geographic location. Plaintiff asserts that harm was foreseeable because each Defendant sold IVIG in the supply chain knowing there was a substantial likelihood the sales were improper due to the illegal payment scenario under which the sales were procured. Plaintiff claims that Defendants failed to guard against foreseeable conduct of corrupt salespeople, corrupt managers, and others within the corporate structure. Further, Plaintiff contends that neither she nor putative class members had CIDP during the period in which the Defendants made the payments and when Brizuela made their diagnoses. Plaintiff raised policy considerations in the Amended Complaint by stating that there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of the Plaintiff. After a period of discovery, it may be that Plaintiff cannot prove the negligence and personal injury claims as a matter of law. At this stage, the allegations are sufficient to establish a plausible claim for negligence and corresponding personal injury.

Defendants' argument regarding the economic loss rule is also misplaced because Plaintiff alleged more than a financial loss. Negligence claims generally require damages from property loss or personal injury. See E. Steel Constructors, Inc. v. City of Salem, 549 S.E.2d 266, 272 (W. Va. 2001). In West Virginia,

an individual who sustains purely economic loss from an interruption in commerce caused by another's negligence may not recover damages in the absence of physical harm to that individual's person or property, a contractual relationship with the alleged tortfeasor, or some other special relationship.

Aikens, 541 S.E.2d at 589. Here, Plaintiff has alleged the side effects, risks, and symptoms associated with IVIG treatment, including fatigue, malaise, fever, nausea, vomiting, headaches, blood pressure changes, tachycardia, acute renal failure, thromboembolic events, aseptic meningitis, neutropenia, and skin reactions. Plaintiff seeks damages for pain and suffering among other losses.

Plaintiff further alleged that a special relationship existed between the parties because there was foreseeable risk that individuals would be misdiagnosed with CIDP and referred for IVIG therapy because of the wrongful payments to Brizuela. Defendants cite Henry v. Synchrony Bank, No. CV 3:16-5999, 2016 WL 6871269 (S.D. W. Va. Nov. 21, 2016) in support of the argument that Plaintiff may not recover economic losses in the absence of personal injury or property damage. However, the Court in Henry

did not dismiss at the 12(b)(6) stage, finding that it was unclear whether Plaintiff could establish a special relationship with Defendant to maintain the action and that the complaint stated a plausible claim for recovery. Henry, 2016 WL 6871269, at *4. Similarly, Plaintiff's claim should not be dismissed based on the economic loss rule.

Defendants' argument in the alternative, that Plaintiff's negligence claim must fail because Defendants cannot "negligently" aid or abet the tortious conduct of another, is also unpersuasive. West Virginia law recognizes a cause of action and liability for "concert of action." Price v. Halstead, 355 S.E.2d 380 (W. Va. 1987); Courtney v. Courtney, 413 S.E.2d 418 (W. Va. 1991). Courts interpreting West Virginia law have applied this "concert of action" theory to support a variety of actions including holding a third party liable for inducing a physician to breach the fiduciary relationship by disclosing confidential information, Morris v. Consolidation Coal Co., 446 S.E.2d 648, 657 (W. Va. 1994), and holding an individual liable for assisting and encouraging a battery by another on a third party, Barth v. Performance Trucking Co., Inc., 424 S.E.2d 602 (W. Va. 1992). Similarly, this Court has recognized that the West Virginia Human Rights Act provides for a cause of action against individuals who aid or abet an unlawful discriminatory act. See Larry v. Marion County Coal Company, 302 F.Supp.3d 763,776-777 (N.D. W. Va. 2018)

(citing Holsten v. Norandex, Inc., 461 S.E.2d 473 (W. Va. 1995)).

In this case, Plaintiff alleges a concert of action by Defendants to provide wrongful, substantial assistance and encouragement to Felix Brizuela, D.O., which Defendants foreseeably knew would cause harm. Construing the Amended Complaint in the light most favorable to the Plaintiff, as it must, the Court finds that Plaintiff has alleged Defendants knew of each other's tortious conduct and provided substantial assistance or encouragement of such conduct for which Defendants may be liable.

The Court further disagrees with Defendants that dismissal is appropriate because the acts of Felix Brizuela, D.O. in intentionally misdiagnosing Plaintiff and punitive class members with CIDP and referring them for IVIG therapy were an intervening and superseding cause that render Brizuela solely liable for damages. A tortfeasor whose negligence is a "substantial factor in bringing about injuries is not relieved from liability by the intervening acts of third persons if those acts were reasonably foreseeable by the original tortfeasor at the time of his negligent conduct." See Syl. Pt. 13, Anderson v. Moulder, 394 S.E.2d 61 (W. Va. 1990); Syl. Pt. 15, Marcus v. Staubs, 736 S.E.2d 360 (W. Va. 2012).

Plaintiff alleges that Defendants engaged in wrongful conduct to induce the new-book sales of IVIG and continued their wrongful conduct after Brizuela's record number of false diagnosis of CIDP.

Plaintiff further contends that after the diagnosis, Defendants wrongfully obtained Plaintiff's private health information without consent and authorization. As pled, Defendants would not be relieved from liability because Brizuela's wrongful conduct was foreseeable from Defendants' affirmative conduct. Based on the allegations of the Amended Complaint, Counts I and II are not appropriate for dismissal at this stage.

B. Civil Conspiracy

Defendants assert that Count III of the Amended Complaint, a claim for civil conspiracy, must fail because it is not a standalone cause of action and because affiliated companies like Defendants cannot conspire as a matter of law⁶ [Dkt. No. 15-2 at 13-14]. Plaintiff counters that West Virginia law recognizes a cause of action for civil conspiracy, regardless of whether the claim requires an underlying tort or harm resulting from the conspiracy [Dkt. No. 19 at 14]. See Dunn v. Rockwell, 689 S.E.2d 255 (W. Va. 2009); Doe-1 v. Corp. of President of the Church of Jesus Christ of Latter-day Saints, 801 S.E.2d 443 (W. Va. 2017).

⁶ Defendants cite Sherman Antitrust Act cases in support of the contention that affiliated companies under the same parent cannot conspire as a matter of law [Dkt. No. 15-2 at 14]. See Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 777 (1984); and Advanced Health-Care Serv., Inc. v. Radford Community Hosp., 910 F.2d 139, 146 (4th Cir. 1990). Defendants also cite a West Virginia case in support of their argument; however, it also involves antitrust, unfair trade practices, and consumer protection claims. See Princeton Ins. Agency, Inc. v. Erie Ins. Co., 690 S.E.2d 587 (W. Va. 2009).

Plaintiff also responds that the Sherman Antitrust Act cases cited by Defendants do not support the argument that related businesses cannot commit civil conspiracy [Dkt. No. 17-18]. Plaintiff contends that the cases narrowly apply the provisions of the Sherman Act anti-trust law and the manner in which one can satisfy the restraint on trade provision of that Act [Id. at 18].

A civil conspiracy requires (1) "a combination of two or more persons by concerted action" to (2) "accomplish an unlawful purpose or to accomplish some purpose, not itself unlawful, by unlawful means." Dunn, 689 S.E.2d at 268. "A civil conspiracy is ... a legal doctrine under which liability for a tort may be imposed on people who did not actually commit a tort themselves but who shared a common plan for its commission with the actual perpetrator(s)." Syl. Pt. 9, in part, Dunn, 689 S.E.2d 255. A civil conspiracy claim is created by the wrongful acts that injured the plaintiff, and not the conspiracy itself. Id. However, it is not necessary for every member of a conspiracy to be aware of every action taken in furtherance of the conspiracy to find liability. Doe-1, 801 S.E.2d at 473. Doe-1 rejected the argument that demonstration of a duty owed to plaintiff by a conspiracy defendant is an essential element of a civil conspiracy claim. There, a defendant dismissed through summary judgment, argued that he did not owe a duty to the plaintiff, and therefore, could not be found liable for conspiracy. The court rejected the argument and stated:

While this Court has said that "the proponent of a civil conspiracy claim must produce at least circumstantial evidence that each member of the alleged conspiracy shared the same conspiratorial objective and mutual agreement, we have not said that each member of a conspiracy must independently owe a duty to the plaintiff."

Doe-1, 801 S.E.2d at 477.

Plaintiff has alleged facts for an underlying tort fraudulent concealment - and the conspiracy and contributing acts of the Defendants taken in furtherance of the conspiracy. Plaintiff alleges that Defendants conspired through a payment scheme and through manipulation of the prior authorization process to have Brizuela diagnose his patients with CIDP for which Brizuela would prescribe and obtain approval for IVIG infusion therapy. The object to be accomplished by the conspiracy was for Defendants to increase sales of new-book IVIG treatments. The means of accomplishing that object was the alleged wrongful payment and concealed prior authorization scheme used by Defendants with Brizuela. The alleged result of the conspiracy was that Plaintiff and punitive class members were diagnosed with CIDP in record numbers and referred for IVIG infusions they believed to be necessary, as Brizuela became one of the highest volume IVIG prescribers in the United States. Plaintiff has alleged sufficient facts to state a claim for civil conspiracy.

Defendants offer no binding authority that would prohibit affiliated companies from being held liable for civil conspiracy

where the alleged conspiracy involves a participant outside the companies. The Sherman Antitrust Act cases cited by Defendants do not support dismissal of the claims here. Viewing the allegations set forth in the Amended Complaint in favor of Plaintiff, the Court finds that Plaintiff has alleged a plausible claim for civil conspiracy.

C. Fraudulent Concealment

Defendants argue that Plaintiff's fraudulent concealment claim fails because Defendants had no duty to disclose payments or transfers of value made to Brizuela and because Plaintiffs failed to allege an essential element of the claim, justifiable reliance [Dkt. No. 15-2 at 15]. Plaintiff argues that that the Amended Complaint includes sufficient facts to establish acts of concealment by Defendants [Dkt. No. 19 at 18].

Fraudulent concealment involves the concealment of facts by one with knowledge or the means of knowledge, and a duty to disclose, coupled with an intention to mislead or defraud.

Trafalgar House Constr., Inc. v. ZMM, Inc., 567 S.E.2d 294, 300 (W. Va. 2002) (citing Silva v. Stevens, 589 A.2d 852, 857 (Vt. 1991)). In alleging the claim, a party must state with particularity the circumstances constituting fraudulent concealment. Fed. R. Civ. P. 9(b). Fraudulent concealment arises when a party conceals facts, or the means to obtain facts, when they had a duty to disclose, in order to mislead or defraud.

Livingston v. K-Mart Corp., 32 F. Supp. 2d 369, 374-75 (S.D. W. Va. 1998). If a party conceals a fact that is material to the transaction, knowing that the other party is acting on the assumption that no such fact exists, the concealment is as much a fraud as if the existence of the fact were expressly denied. Id. at 375; See Knapp v. Americredit Fin. Servs., 245 F. Supp. 2d 841 (S.D. W. Va. 2003).

Although Defendants argue that Plaintiff has alleged fraudulent concealment in conclusory fashion, the Court cannot agree. Plaintiff alleged wrongful payments to Felix Brizuela, D.O. to increase sales of IVIG products, and failing to disclose the significant geographic spike in the increase of CIDP by Brizuela. Plaintiff also alleged a failure to disclose to Plaintiff and putative class members that their health, safety, and wellbeing were at risk because of payments made to Brizuela for increased referrals for IVIG therapy, and a failure to inform Plaintiff of Brizuela's disclosure of private health, financial, and identifying information to Defendants without Plaintiff's consent or authorization. Plaintiff likewise alleged that she reasonably believed that the referral for IVIG therapy was necessary and she agreed to the purchase of IVIG infusions in reliance upon that reasonable belief. These allegations identify specific acts by Defendants; therefore, Plaintiff has stated a

plausible claim for fraudulent concealment which is all the Rule 12(b)(6) threshold requires and dismissal of Count IV is not warranted.

D. Unjust Enrichment/Disgorgement

Defendants argue that the failure of Plaintiff's fraudulent concealment claim is similarly fatal to the claim for unjust enrichment [Dkt. No. 15-2 at 16]. Plaintiff counters that she has pled factual allegations sufficient to state a claim [Dkt. No. 19 at 19-20].

If "benefits have been received and retained under such circumstances that it would be inequitable and unconscionable to permit the party receiving them to avoid payment therefor, the law requires the party receiving the benefits to pay their reasonable value."

Realmark Developments, Inc. v. Ranson, 542 S.E.2d 880, 884-85 (W. Va. 2000). The right to recover for unjust enrichment is based on the principles of equity. "Unjust enrichment ... is but the equitable reason for requiring payment for value of goods and services received."

Realmark Developments, Inc. v. Ranson, 588 S.E.2d 150, 153 (W. Va. 2003) (quoting Nehi Beverage Co., Inc. of Indianapolis v. Petri, 537 N.E.2d 78, 85 (Ind.Ct.App. 1989).

The Amended Complaint alleged that Defendants concealed wrongful payments to Brizuela and that Plaintiff was not aware of the concealed payments which triggered her diagnosis of CIDP and referral for IVIG therapy until April 2019. Plaintiff also alleged

that she and putative class members reasonably relied upon Defendants to engage in legal marketing and sales practices and they would not have purchased IVIG from Defendants if the concealed payment scheme were disclosed. Finally, Plaintiff alleged that Defendants were unjustly enriched by their conduct and have failed to reimburse Plaintiff and putative class members for their unjust enrichment. Plaintiff alleged sufficient facts to state a plausible claim for unjust enrichment and dismissal of Count V under Rule 12(b)(6) is improper.

E. Breach of Confidentiality and Violation of Privacy

Defendants contend there is no basis for Plaintiff's claim at Count VI for breach of confidentiality and violation of privacy because laws governing the security and confidentiality of personal health information, such as the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), make clear that the disclosure of information from one health care provider to other health care providers or third parties for treatment, payment, and health care operations is permissible without the consent of the patient [Dkt. No.15-2 at 17]. Plaintiff claims that her cause of action arises under West Virginia case law which recognizes an individual's right to privacy with respect to medical records and medical information regardless of HIPAA [Dkt. No. 19 at 20].

The Fourth Circuit has noted that Congress, through HIPAA, intended to recognize "the importance of protecting the privacy of health information in the midst of the rapid evolution of health information systems." S.C. Med. Ass'n v. Thompson, 327 F.3d 346, 348 (4th Cir. 2003). HIPAA regulations, at 45 C.F.R. § 164.506, allow a covered entity to use or disclose "protected health information for treatment, payment, or health care operations," without prior authorization or consent. Under the regulation, "payment" includes obtaining or providing "reimbursement for the provision of health care" such as eligibility or coverage determinations and the review of "health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges." 45 C.F.R. § 164.501. The term "treatment" includes "the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another." Id.

West Virginia recognizes a cause of action against a third party for the inducement of an improper disclosure of private medical information:

A patient does have a cause of action against a third

party who induces a physician to breach his fiduciary relationship if the following elements are met: (1) the third party knew or reasonably should have known of the existence of the physician-patient relationship; (2) the third party intended to induce the physician to wrongfully disclose information about the patient or the third party should have reasonably anticipated that his actions would induce the physician to wrongfully disclose such information; (3) the third party did not reasonably believe that the physician could disclose that information to the third party without violating the duty of confidentiality that the physician owed the (4) physician wrongfully divulges patient; the confidentiality information to the third party.

Syl. Pt. 5, Morris v. Consolidation Coal Co., 446 S.E.2d 648 (W. Va. 1994). Common law "tort claims based upon the wrongful disclosure of medical or personal health information are not preempted by the Health Insurance Portability and Accountability Act of 1996." R.K. v. St. Mary's Medical Center, Inc., 735 S.E.2d 715, 724 (W. Va. 2012). Moreover, an allegation "which pertain[s] to the improper disclosure of medical records, does not fall within the MPLA7 definition of "health care" and, therefore, the MPLA does not apply." Id. at 727.

As Plaintiff notes, 45 C.F.R. § 164.506 specifically exempts any use or disclosure of health care information that requires an authorization as set forth in 45 C.F.R. § 164.508(a)(2)-(4). Provision 45 C.F.R. § 164.508(a)(3) requires an authorization for marketing where the marketing involves financial remuneration, and

 $^{^{7}}$ The MPLA is a reference to The West Virginia Medical Professional Liability Act, codified at 55-7B-1 et seq. of the West Virginia Code.

the authorization must state that such remuneration is involved. The provision at 45 C.F.R. § 164.508(a)(4) requires an authorization for any disclosure of protected health information that is a sale of the protected health information. Furthermore, 45 C.F.R. § 164.502(b) requires that only the minimum necessary elements of protected health information should be obtained.

In the Amended Complaint, Plaintiff asserted facts that arguably establishes a claim for breach of confidentiality and violation of privacy. Plaintiff alleged that Defendants obtained Plaintiff's and putative class members' private health, financial, identifying information without their consent authorization. Plaintiff also alleged that Defendants wrongfully induced Brizuela to provide access to Plaintiff's and putative class members' private information through wrongful payments intended to increase IVIG sales. Because West Virginia recognizes a cause of action independent from HIPAA for the improper disclosure of private medical information, the allegations of the Amended Complaint state a plausible claim for recovery. Dismissal of Count VI is not warranted.

F. Punitive Damages

Plaintiff's Amended Complaint includes at Count VII a claim titled "Punitive Damages" [Dkt. No. 9 at 21]. Plaintiff concedes that a claim for Punitive Damages should not be asserted as a separate cause of action, and instead is a remedy for relief sought

as part of the other claims asserted [Dkt. No. 19 at 25]. Plaintiff requests the opportunity to designate the remedy in the Prayer for Relief to the extent it is not already included [Id.]. The Court notes that punitive damages are included in the Prayer for Relief in the Amended Complaint [Dkt. 9 at 22]. Considering Plaintiff's concession, Defendants' request to dismiss Count VII is moot.

G. The Medical Professional Liability Act

Defendants include as grounds for their motion to dismiss an argument that Plaintiff failed to comply with the pre-suit notice requirements of the MPLA which is fatal to Plaintiff's case [Dkt. No. 15-2 at 19]. A claim is governed by the MPLA if a plaintiff alleges medical professional liability against a health care provider or health care facility while rendering health care services. W. Va. Code § 55-7B-4(a); See Manor Care, Inc. v. Douglas, 763 S.E.2d 73, 87 (W. Va. 2014). "Medical professional liability" is defined as "liability for damages resulting from the death or injury of a person for any tort or breach of contract based on health care services rendered, or which should have been rendered, by a health care provider or health care facility to a patient." W. Va. Code § 55-7B-2(i). This includes "other claims that may be contemporaneous to or related to the alleged tort ... in the context of rendering health care services." Id.

The MPLA defines "health care providers" and "health care facilities" to include pharmacies and related entities. W. Va.

Code § 55-7B-2(g)-(f), (n). The statute defines "[h]ealth care" as:

(1) [a]ny act, service or treatment provided under, pursuant to or in the furtherance of a physician's plan of care, a health care facility's plan of care, medical diagnosis or treatment [and] (2) [a]ny act, service or treatment performed or furnished, by any health care provider or person supervised by or acting under the direction of a health care provider or licensed professional for, to or on behalf of a patient during the patient's medical care....

Id. at § 55-7B-2(e)(1)-(2). Pursuant to the MPLA, "no person may file a medical professional liability action against any [health care facility or related entity] without complying with" the presuit notice requirements. W. Va. Code § 55-7B-6(a).

When a defendant asserts it is entitled to the protections provided by the MPLA, the defendant is required to provide an explanation of the nature and basis for claiming that the act applies to Defendant and how its pre-suit notification rights have been violated. See Hinchman v. Gillette, 618 S.E.2d 387 (W. Va. 2005); Boggs v. Camden-Clark Memorial Hospital Corp., 609 S.E.2d 917 (W. Va. 2004). Plaintiff contends that Defendants have not provided a Hinchman letter identifying which Defendant claims to be a health care provider within the meaning of the MPLA, outlining the care provided to Plaintiff, and the manner in which the health care is encompassed by Plaintiff's claims [Dkt. No. 19 at 23]. Plaintiff argues that, to the extent the Court finds she did not comply with pre-suit notification requirements of the MPLA,

dismissal is inappropriate and Plaintiff should be provided an opportunity to amend the claim so that it may be addressed on the merits. See Gray v. Mena, 625 S.E.2d 326 (W. Va. 2005).

Defendants demand dismissal because US Bioservices is licensed with the West Virginia Board of Pharmacy, of which Defendants ask the Court take judicial notice, and Plaintiff was referred to US Bioservices for IVIG therapy [Dkt. No. 20 at 3]. Plaintiff notes that Defendants, including US Bioservices, provided no health care services required to administer IVIG therapy, and instead contracted with an entity unaffiliated with Defendants, Critchfield Specialty Infusion, to perform the infusion of the IVIG product marketed and distributed by Defendants [Dkt. No. 19 at 22-23 and Exh. 1]. Plaintiff also asserts that the claims arise from Defendants' wrongful payments to and influence on Felix Brizuela, D.O. rather than the provision of legitimate health care services [Id.].

In West Virginia, the <u>Hinchman</u> Court was careful to articulate that the "requirement of pre-suit notice of claim and screening certificate of merit is not intended to restrict or deny citizens' access to the courts." <u>Hinchman</u>, 625 S.E.2d at 388, Syl. Pt. 2, in part. The Court also noted that the purpose of statutes impacting rights of litigants is not to create some breed of gamesmanship. <u>Id.</u> at 394.

The Court is not convinced that dismissal of Plaintiff's

claims based on a failure to comply with the MPLA is proper under Rule 12(b)(6) considering the factual allegations set forth in the Amended Complaint. Although US Bioservices is licensed with the West Virginia Board of Pharmacy, at this time, it is unclear whether Defendants are entitled to the protections of the MPLA as having provided health care services to Plaintiff and putative class members. The Hinchman Court explained that, in reviewing a claim of insufficiency of notice, "a principal consideration ... should be whether a party challenging or defending the sufficiency of a notice and certificate has demonstrated a good faith and reasonable effort to further the statutory purposes." Hinchman, 618 S.E.2d at 395. The circumstances presented here do not necessitate dismissal. Rather, Defendants should outline for Plaintiff the health care services they provided Plaintiff within the meaning of the MPLA, such that a pre-suit notification was required, and Plaintiff should seek leave to amend the claims so that they may be addressed on the merits.

IV. CONCLUSION

For the reasons stated above, the Court's Order [Dkt. No. 36] is **AMENDED** to the extent that the motion to dismiss [Dkt. No. 15] is **DENIED** as to Counts I, II, III, IV, V, and VI, and **DENIED AS MOOT** as to Count VII. The Court further **DENIES** the motion to dismiss based on the MPLA.

The Court ORDERS the parties to MEET AND CONFER regarding the

MPLA issue and before Plaintiff files a Second Amended Complaint if such filing is deemed necessary. The Court **DIRECTS** the parties to file a **JOINT STATUS REPORT** by no later than **December 21, 2020**, to certify that they have met and conferred.

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to counsel of record.

DATED: November 2, 2020

/s/ Thomas S. Kleeh
THOMAS S. KLEEH
UNITED STATES DISTRICT JUDGE